Cyclacel Pharmaceuticals To Present Preliminary Data From The Phase 1/2 Clinical Trial Of Oral Fadraciclib At The 34th EORTC-NCI-AACR Symposium

October 13, 2022

- Preliminary Dose Escalation Data to be Presented on Novel CDK2/9 Inhibitor Fadraciclib in Patients with Solid Tumors and Lymphoma -

BERKELEY HEIGHTS, N.J., Oct. 13, 2022 (GLOBE NEWSWIRE) -- Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC, NASDAQ: CYCCP; "Cyclacel" or the "Company"), a biopharmaceutical company developing innovative medicines based on cancer cell biology, today announced it will present preliminary dose escalation data from its ongoing 065-101 Phase 1/2 clinical trial of oral fadraciclib for the treatment of patients with advanced solid tumors and lymphoma during a poster presentation at the upcoming 34th EORTC-NCI-AACR (ENA) Symposium on Molecular Targets and Cancer Therapeutics, which is being held on October 26-28th, 2022, in Barcelona, Spain.

Details of the presentation are provided below:

Title:	A Phase 1/2, Open-label, Multi-center Study to Investigate the Safety, Pharmacokinetics, and Efficacy of Fadraciclib (CYC065), an Oral CDK2/9 Inhibitor, in Subjects with Advanced Solid Tumors and Lymphoma
Abstract No:	50
Session Topic:	Molecular Targeted Agents 1
Date and Time:	Wednesday, October 26, 2022, 12:00 – 20:00 CEST
Location:	Exhibition Hall

About Cyclin-Dependent Kinases and Fadraciclib
Cyclin-dependent kinases (CDKs) are critical for cell cycle control and transcriptional regulation. Dysregulated CDKs have been linked to the cancer hallmarks of uncontrolled proliferation and increased cancer cell survival. Fadraciclib, a next generation CDK inhibitor, is a highly selective, potent, orally and intravenously available, inhibitor of CDK2 and CDK9. CDK2 drives cell cycle transitions and CDK9 regulates transcription of genes through phosphorylation of the carboxy-terminal domain (CTD) of RNA polymerase II (RNAP II). By inhibiting CDK2 and CDK9 fadraciclib causes apoptotic death of cancer cells at sub-micromolar concentrations. Fadraciclib is being tested in a Phase 1/2 trial for the treatment of advanced solid tumors and lymphoma (065-101; NCT#04983810) and a Phase 1/2 trial for the treatment of hematological malignancies (065-102; NCT#05168904).

Preclinical data suggest that fadraciclib may benefit patients with certain cyclin E-addicted or MYC-amplified solid tumors, including certain forms of breast cancer, neuroblastoma, ovarian cancer, uterine serous carcinoma and adult and pediatric hematological malignancies, such as ALL, AML, B-cell lymphoma, CLL, and multiple myeloma. Similarly to FDA-approved CDK4/6 inhibitors, fadraciclib may be useful in combination with other anticancer drugs, including HER2 inhibitors, such as trastuzumab, or BCL2 inhibitors, such as venetoclax.

In a prior Phase 1 open-label trial (CYC065-01), patients with high copy CCNE (cyclin E), MYC or MCL1 showed sensitivity to intravenously administered, single-agent fadraciclib. A heavily pretreated patient with MCL1 amplified endometrial cancer achieved a radiographically confirmed partial response (PR) after a month and a half on fadraciclib, subsequently achieved CR and continues on treatment with fadraciclib for over three years. An additional patient with cyclin E amplified ovarian cancer achieved stable disease with 29% shrinkage in her target tumor lesions.

About Cyclacel Pharmaceuticals, Inc.

Cyclacel is a clinical-stage, biopharmaceutical company developing innovative cancer medicines based on cell cycle, transcriptional regulation and mitosis biology. The transcriptional regulation program is evaluating fadraciclib, a CDK2/9 inhibitor, and the anti-mitotic program CYC140, a PLK1 inhibitor, in patients with both solid tumors and hematological malignancies. Cyclacel's strategy is to build a diversified biopharmaceutical business based on a pipeline of novel drug candidates addressing oncology and hematology indications. For additional information, please visit www.cyclacel.com.

Forward-looking Statements
This news release contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, the efficacy, safety and intended utilization of Cyclacel's product candidates, the conduct and results of future clinical trials, plans regarding regulatory filings, future research and clinical trials and plans regarding partnering activities. Factors that may cause actual results to differ materially include the risk that product candidates that appeared promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later clinical trials, trials may have difficulty enrolling, Cyclacel may not obtain approval to market its product candidates, the risks associated with reliance on outside financing to meet capital requirements, the potential effects of the COVID-19 pandemic, and the risks associated with reliance on collaborative partners for further clinical trials, development and commercialization of product candidates. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "forecast," "designed," "goal," or the negative of those words or other comparable words to be uncertain and forward-looking. For a further list and description of the risks and uncertainties the Company faces, please refer to our most recent Annual Report on Form 10-K and other periodic and other filings we file with the Securities and Exchange Commission and are available

at www.sec.gov. Such forward-looking statements are current only as of the date they are made, and we assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Contacts

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